

REMARKS

In the Office Action, claims 1-40 were rejected. By the present Response, claims 1, 14, 17, 30, and 33 are amended. No new matter has been added. Upon entry of the amendments, claims 1-40 will remain pending in the present patent application. In view of the foregoing amendments and the following remarks, the Applicants respectfully request reconsideration and allowance of all pending claims.

Rejections Under 35 U.S.C. § 102

In the present Office Action, claims 1-9, 13-25, and 29-35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brown, U.S. Patent No. 6,196,970 (hereinafter "Brown"). Applicants respectfully traverse this rejection.

Legal Precedent

The Applicants respectfully submit that the cited reference does not anticipate the pending claims. Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *See Titanium Metals Corp. v. Banner*, 227 U.S.P.Q. 773 (Fed. Cir.1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir.1990). That is, the prior art reference must show the *identical invention "in as complete detail as contained in the ... claim"* to support a *prima facie* case of anticipation. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). Thus, for anticipation, the cited reference must not only disclose all of the recited features but must also disclose the *part-to-part relationships* between these features. *See Lindermann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 U.S.P.Q. 481, 486 (Fed. Cir.1984). Accordingly, Applicants need only point to a single element or claimed relationship not found in the cited reference to demonstrate that the cited reference fails to anticipate the claimed subject matter. A *strict correspondence* between the claimed language and the cited reference must be established for a valid anticipation rejection.

Moreover, the Applicants submit that, during patent examination, the pending claims must be given an interpretation that is *reasonable* and *consistent* with the specification. *See In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *In re Morris*, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also M.P.E.P. § 2111 (describing the standards for claim interpretation during prosecution). Indeed, the *specification* is “the primary basis for construing the claims.” *See Phillips v. AWH Corp.*, No. 03-1269, -1286, at 13-16 (Fed. Cir. July 12, 2005) (citations omitted). It is usually dispositive. *See id.* Interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *See In re Cortright*, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); see also M.P.E.P. § 2111. That is, recitations of a claim must be read as they would be interpreted by those of ordinary skill in the art. *See Rexnord Corp. v. Laliram Corp.*, 60 U.S.P.Q.2d 1851, 1854 (Fed. Cir. 2001); see also M.P.E.P. § 2111.01. In summary, an Examiner, during prosecution, must interpret a claim recitation as one of ordinary skill in the art would reasonably interpret the claim in view of the specification. *See In re American Academy of Science Tech Center*, 70 U.S.P.Q.2d 1827 (Fed. Cir. 2004). With the foregoing legal precedent in mind, the Applicants address the Section 102 rejection below.

Independent claims 1, 17, and 33

Turning now to the claims, amended independent claims 1, 17, and 33 respectively recite a method, a system, and a computer program, comprising, *inter alia*, “[clinical study (CS)] information being entered through a *user selected template*” wherein the “user selected template is selected from a plurality of templates stored in a centralized database, each of the plurality of templates configured to correspond to specific clinical studies.” (Emphasis added). Applicants respectfully assert that Brown fails to disclose each and every feature of the independent claims 1, 17, and 33.

First, it does not appear that Brown teaches or suggests *selecting a template from a plurality of templates stored in a centralized database*. In rejecting independent claims

1, 17, and 33, the Examiner correlated “a protocol” of Brown with the “plurality of templates” of the present claims. *See* Office Action, pages 3, 8, 11-12. Specifically, the Examiner stated “[i]t is noted that the protocol is considered to be a plurality of templates.” *Id.* The server device 130, as described by Brown, appears to be configured to store the information and protocol 131 into the database 132. *See* Brown, col. 6, lines 9-12; Fig. 1 (it should be noted, however, that Fig. 1 of Brown shows a server device 130 containing the protocol 131 and the database 132 as *separate and distinct structures*). Thus, while the database 132 of Brown may store the protocol sent by the medical research expert, it does not appear that the protocol is *selected from* a plurality of protocols stored in the database 132, as recited by the independent claims. In sharp contrast, Brown describes a user (medical expert 121) entering research information and a protocol 131 into a medical research expert device 120. *See id.*, col. 6, lines 1-4. The research information and protocol are then sent to a server device 130 using a communication network 140. *See id.*, col. 6, lines 5-8. In other words, the protocol is selected by a user and *subsequently* transmitted to the server device for storage in the database. However, the protocol is *clearly not selected from a plurality of templates in the database*.

Secondly, Applicants believe that the Examiner’s correlation of “a protocol” to “plurality of templates,” as recited in the present claims, is erroneous. The two are simply not comparable. As defined in Brown, a “protocol” is a type of *message* which appears to help automate operation of research subject devices and medical expert research devices. *See* Brown, Fig. 1. In a medical or clinical study, medical experts may often be required to monitor and oversee the collection of clinical data and *manipulate or operate* the medical expert research devices as necessary, based on data received from the research subjects. *See id.* col. 3, lines 41-63. For example, Brown states that “system 100 collects and analyzes data from participating from human subjects using a *protocol or other intelligent message*, which acts in place of a researcher, investigator, clinician, or medical expert. *See id.*, Fig. 1; col. 4, lines 63-67. (Emphasis added). Indeed, the protocols

appear to be instructional messages for operating medical research equipment, thus reducing the need for constant supervision by the medical expert.

In contrast, the meaning of a “template,” as recited by the independent claims, is focused on a device or interface having a set of fields allowing “a user to enter specific CS (clinical study) data 92 or to display specific CS data 92 for a user to view and analyze.” Application, paragraph 35, lines 8-10. Moreover, the information entered into the *user template* is used to gather *protocols* for operating medical devices. *See id.*, paragraph 8, lines 5-8. Application, remind the Examiner that, during patent examination, the pending claims must be given an interpretation that is *reasonable* and *consistent* with the specification. *See In re Prater*, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969). Indeed, in the present context, a template clearly includes a set of fields used to gather information. It is not, as the Examiner suggests, analogous to a protocol. Brown does not teach or suggest that a *protocol* is developed as a result of clinical information entered through a *template* or that a “protocol” allows user entry of CS data or the display of such data. As such, Applicants assert that Brown does *not* teach or suggest a template, much less a *plurality of templates*, as recited by independent claims 1, 17, and 33.

For at least the reasons set forth above, the Examiner has not established a *prima facie* case of anticipation against independent claims 1, 17, and 33. Accordingly, Applicants respectfully request withdrawal of the rejections of independent claims 1, 17, and 33, as well as the claims depending therefrom, under 35 U.S.C. § 102.

Independent claims 14 and 30

Applicants assert that Brown also fails to disclose each and every feature recited by amended independent claims 14 and 30. Independent claim 14, as amended, recites, *inter alia*, “using a template *selected by a user from a plurality of templates stored in a centralized database* . . . to gather protocols for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific

clinical studies.” (Emphasis added). Independent claim 30, as amended, recites a server system configured to “use a template *selected by a user from the plurality of templates stored in the centralized database* to gather protocols for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific clinical studies.” Amended claims 14 and 30 recite subject matter similar to that recited by amended independent claims 1, 17 and 33. Thus, for the reasons discussed above with regards to independent claims 1, 17, and 33, the Examiner has not established a *prima facie* case of anticipation against independent claims 14 and 30. Accordingly, Applicants respectfully request withdrawal of the rejections of independent claims 14 and 30, as well as the claims depending therefrom, under 35 U.S.C. § 102.

Rejections Under 35 U.S.C. § 103

In the present Office Action, the Examiner rejected under 35 U.S.C. § 103(a): claims 4-5, 14-16, 20-21, 30-32, and 34-35 as obvious over Brown in view of Goldwasser, U.S. Patent No. 4,737,921 (hereinafter “Goldwasser”); claims 10-11, 26-27, and 39-40 as obvious over Brown in view of Rice, U.S. Publication No. 2002/0042723 (hereinafter “Rice”); and claims 12 and 28 obvious over Brown in view of Official Notice. Applicants respectfully traverse this rejection.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). The Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). In addressing obviousness determinations under 35 U.S.C. § 103, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), reaffirmed many of its precedents relating to obviousness including its holding in *Graham v. John Deere Co.*,

383 U.S. 1 (1966). In *KSR*, the Court also reaffirmed that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 14. In this regard, the *KSR* court stated that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does ... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 14-15. In *KSR*, the court noted that the demonstration of a teaching, suggestion, or motivation to combine provides a “helpful insight” in determining whether claimed subject matter is obvious. *KSR, slip op.* at 14.

Independent claims 14 and 30

Amended independent claims 14 and 30, as amended, recite, *inter alia*, “a template selected by a user from said plurality of templates stored in a centralized database . . . to gather *protocols* for acquisition of image data via the at least one medical device, each of the plurality of templates configured to correspond to specific clinical studies.” (Emphasis added). As discussed above, Brown fails to disclose each and every element of claims 14 and 30. Goldwasser fails to obviate the deficiencies of Brown. Specifically, Goldwasser does not teach or suggest *selecting a template from plurality of templates stored in a centralized database*. In view of these deficiencies, among others, Brown and Goldwasser, taken alone or in hypothetical combination, cannot render obvious the current independent claims 14 and 30 and their respective dependent claims.

Claims 4-5, 20-21, and 34-35

The Examiner rejected dependent claims 4-5, 20-21, and 34-35 as being unpatentable over Brown in view of Goldwasser. However, Goldwasser fails to obviate the deficiencies of Brown, as discussed above. As such, claims 4-5, 20-21, and 34-35 are believed to be clearly patentable at least by virtue of their dependency from an allowable parent claim.

Claims 10-11, 26-27, and 39-40

The Examiner rejected dependent claims 10-11, 26-27, and 39-40 as being unpatentable over Brown in view of Rice. However, Rice fails to obviate the deficiencies of Brown because it does not teach or suggest *selecting a template from plurality of templates stored in a centralized database*, as recited by parent claims 1, 17, and 33. As such, claims 10-11, 26-27, and 39-40 are also believed to be clearly patentable at least by virtue of their dependency from an allowable parent claim.

Claims 12 and 28

The Examiner rejected dependent claims 12 and 28 as being unpatentable over Brown in view of Official Notice. Specifically, the Examiner stated that “(a) forming a query; (b) transmitting the query to the database; (c) parsing of the query by the database; (d) retrieving information stored in the database as indicated by the result of (c); [and] (e) returning the result of (d) for display; is old and well established in the art of database.” Office Action, page 14. However, as discussed above, Brown does not disclose a *selecting a template from plurality of templates stored in a centralized database*, as recited by parent claims 1 and 17, and Official Notice does not cure these deficiencies. As such, claims 12 and 28 are believed to be clearly patentable at least by virtue of their dependency from an allowable parent claim.

Moreover, Applicants challenge the Examiner’s use of Official Notice. Even if the general query steps of claims 12 and 28 could be inferred from unidentified art, the Examiner still bears the burden of establishing a *prima facie* case based upon a reasonable combination with Brown and some likelihood of success. In this case, Brown does not disclose entering information into a database in the manner set forth in claim 1 (or 17). As such, the query steps of claims 12 and 28 do not appear

combinable with Brown. The mere citation of Official Notice does not provide the requisite likelihood of success in this regard, and is therefore traversed.

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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